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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,051	08/08/2006	Kohichi Tanaka	023312-0118	5841

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EXAMINER

SAJJADI, FEREDOUN GHOTB

ART UNIT	PAPER NUMBER
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1633

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,051	Applicant(s) TANAKA ET AL.	
	Examiner FEREYDOUN G. SAJJADI	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2 and 5-14 is/are pending in the application.
- 4a) Of the above claim(s) 8-10 and 12-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 5-7 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/12/2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Status

Applicants' response of February 14, 2008, to the non-final action dated November 14, 2007 has been entered. Claims 2 and 5-14 are pending in the application. Claims 2, 5 and 11 have been amended. No claims were cancelled or newly added. Claims 8-10 and 12-14 stand withdrawn from further consideration, with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Claims 2, 5-7 and 11 are under current examination.

Response to Information Disclosure Statement

The information disclosure statement filed 10/12/2005 fails to comply with 37 CFR 1.98(a)(2); as several references were not present in the instant application. Applicants state that copies of the missing foreign patent documents and literature articles have been submitted; however no such copies appear in the file record. Thus the references remain unconsidered.

Response and New Claim Rejections - 35 USC § 112- Second Paragraph

Applicants' claim amendments have necessitated the following new grounds of rejection.

Claim 5 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite, in the previous office action dated November 14, 2007. Applicants' claim amendments deleting the indefinite claim language and language lacking an antecedent basis, while obviating the grounds of rejection, render the claim indefinite as follows:

Claim 5 is ambiguous. The claim is drawn to a GLAST knockout mouse according to claim 2, wherein all genotypes other than the targeted genotype (GLAST genotype) are the same by 99% or more with that of a C57BL/6 strain mouse.

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It should be noted that a genotype may be defined as all or part of the genetic constitution of an individual (Merriam-Webster online dictionary). As a mouse contains one single genome and one genotype, it is not clear how a knockout mouse can comprise multiple genotypes as instantly claimed.

Claim 5 lacks an antecedent basis for “all genotypes”. Amendment of the claim to recite “wherein the genetic background of said mouse, except for the targeted endogenous GLAST gene is the same by 99% or more as that of a C57BL/6 strain mouse” would be remedial.

Claim 11 is newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is drawn to a homozygous or heterozygous GLAST knockout mouse produced by a method comprising 6 distinct steps. Applicants have amended claim 11 (a product claim) to incorporate the method steps of withdrawn claim 9 (non-elected subjected matter). The claim is therefore at once drawn to a product and a method. As stated in MPEP 2173.05(p)II, a single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. 112, second paragraph. *IPXL Holdings v. Amazon.com, Inc.*, 430 F.2d 1377, 1384, 77 USPQ2d 1140, 1145 (Fed. Cir. 2005); *Ex parte Lyell*, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990) (claim directed to an automatic transmission workstand and the method of using it held ambiguous and properly rejected under 35 U.S.C. 112, second paragraph). Such claims may also be rejected under 35 U.S.C. 101 based on the theory that the claim is directed to neither a “process” nor a “machine,” but rather embraces or overlaps two different statutory classes of invention set forth in 35 U.S.C. 101 which is drafted so as to set forth the statutory classes of invention in the alternative only.

Response to Claim Rejections - 35 USC § 102

Claim 11 was previously rejected under 35 U.S.C. 102(b) as being anticipated by Watase et al. (Eur. J. Neurosci. 10:976-988; 1998), in the office action dated November 14, 2007. Applicants' claim amendments incorporating various genetic crosses not taught by the cited

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reference obviate the grounds of rejection. Accordingly the rejection is hereby withdrawn.

Applicants' arguments are rendered moot in view of the withdrawn rejection.

Response and New Claim Rejections - 35 USC § 103

Applicants' claim amendments have necessitated the following new grounds of rejection.

Claims 2, and 5-7 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Watase et al. (Eur. J. Neurosci. 10:976-988; 1998), in view of Chitnis et al. (J. Clin. Invest. 108(5):739-747; 2001). The rejection set forth on pp. 5-7 of the previous office action dated November 14, 2007 is applied to amended claim 11 for reasons of record.

Applicants disagree with the rejection, arguing that the while Watase et al. discloses a homozygous or heterozygous GLAST knockout mouse, such mouse cannot be used as a model for normal tension glaucoma unless ischemic load is applied. Applicants' arguments have been fully considered, but are not found persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The instant claims have not been rejected in view of the teachings of Watase et al. alone.

The claims encompass a transgenic GLAST knockout mouse deficient in the function of an endogenous GLAST gene, wherein a neomycin-resistant gene is inserted into exon 6 of said GLAST gene, and wherein the genetic background of said knockout mouse is substantially the same as the genetic background of a C57BL/6 strain mouse.

Watase et al. describe the inactivation of the mouse GLAST gene (Abstract) following the targeted disruption of the endogenous mouse GLAST gene in ES cells, the generation of chimeric mice by injecting targeted ES cells into C57BL/6 blastocysts and germline transmission of the targeted mutation in the GLAST gene to generate homozygous and heterozygous mutants (first column, p. 978). The production of GLAST mutant mice by targeted disruption of exon 6 with insertion of a Neo gene is described on p. 978, first column and Fig. 1, p. 979, and include the generation of heterozygous and homozygous mutant mice containing the targeted GLAST gene (first column, p. 978).

While Watase et al. do not describe the details of genetic crosses or backcrosses used to derive the heterozygous and homozygous GLAST knockout mice, such cross breeding was known in the art of transgenic mouse production at the time, and must have necessarily been

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employed to produce the knockout mice. Nonetheless, at least the generation of GLAST mutations in a C57BL/6 chimeric background are explicitly taught by Watase et al. Chitnis et al. describe the effect of targeted disruption of mouse STAT genes in knockout mice (Abstract). Additionally describe the backcross of said knockout mice onto a C57BL/6 background for at least ten generations (first column, p. 740).

Applicants have ignored the teachings of Chitnis et al. for the multigenerational backcross to a C57BL/6 genetic background to produce an inbred GLAST knockout mouse having less genotypic and phenotypic background variation.

Applicants state that base claim 2 has been amended to incorporate the phrase “when ischemic load is not applied” to obviate the rejection. Such is not found persuasive, because a GLAST knockout mouse generated by a person of ordinary skill in the art following the combined teachings of Watase et al. and Chitnis et al. would necessarily produce the instantly claimed mouse wherein the genetic background is substantially the same as the genetic background of a C57BL/6 strain mouse and an intraocular pressure that is not greater than 21mmHg and the number of cells in the retinal ganglion is reduced by at least 20% when ischemic load is not applied, as such properties would be inherent to said mouse.

As previously indicated, a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). As indicated in MPEP 2112, the express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103. “The inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness.” *In re Napier*, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995).

Thus the rejection of claims 2 and 5-7 is maintained and further applied to claim 11, for reasons of record.

Conclusion

Claims 2, 5-7 and 11 are not allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. The claims are drawn to the same invention claimed earlier in the application and would have been finally rejected on the grounds and art of record in the next Office Action if they had been entered earlier in the application. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FEREDYDOUN G. SAJJADI whose telephone number is (571)272-3311. The examiner can normally be reached on 6:30 AM-3:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Fereydoun G Sajjadi/

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